REMARKS

Applicant has reviewed the cited art and the Examiner's comments, and requests favorable reconsideration in view of the following remarks. In the Office Action mailed June 17, 2010, the Examiner rejected all pending claims 1-5, 7-8, 15-19 and 21-22 under 35 U.S.C. § 103(a) as being unpatentable over Reiss (USP 5,512,057) in view of Holsheimer (US 5,643,330).

I. Summary of Examiner Interview

Applicant thanks the Examiner for the telephone interview on August 10, 2010. During the interview, Applicant and the Examiner discussed the rejection of the claims over Reiss in view of Holsheimer, and the Declaration of William Carroll under 37 CFR § 1.132 filed on March 10, 2010 ("the Declaration").

Applicant noted that the Examiner stated in the Final Office Action mailed June 17, 2010, that Applicant's Declaration is directed against the references individually, and that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. *Office Action*, 6.17.10, p. 4. Applicant stated that although evidence of experimental results must compare the claimed invention with the closest prior art, Applicant is not required to compare the claimed invention with subject matter that does not exist. (MPEP § 716.02(e)(III)). Requiring Applicant to compare a claimed invention with that suggested by the combination of references relied upon in the rejection of the claimed invention under 35 U.S.C. 103 "would be requiring comparison of the results of the invention with the results of the invention." *In re Chapman*, 357 F.2d 418, 422 (CCPA 1966). (MPEP § 716.02(e)(III)). The Examiner agreed with the Applicant and indicated that this objection would be withdrawn.

Applicant further described how the Declaration does not substantially change the scope of the claimed invention. The claims recite "first and second sinusoidal signals having different

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first and second frequencies with a base medium frequency of at least 500Hz but no more than 20KHz," and in paragraphs 16 and 22 of the Declaration, Applicant explained that the applied stimulation frequency was a first wave pulse of a sinus wave of about 500 μs width (corresponding to about 2000 Hz waves) applied at a frequency of about 100 Hz and a second wave pulse of a sinus waves of about 476 μs width (corresponding to about 2100 Hz) applied at a frequency of about 105 Hz to the other set of electrode pairs to create an interference pattern.

Applicant proposed amendments to the claims as made in the present amendment, and the Examiner stated that the Declaration would be given more weight as evidence of non-obviousness in view of such amendments. The Examiner stated that if the claims were amended in the present manner, the present rejections under 35 U.S.C. § 103 would be overcome.

II. Status of Claims

Claims 1-5, 7-8, 15-19 and 21-22 are pending. Applicant has amended claim 1 to recite "wherein a majority of the at least one beat frequency signal is directionally distributed and controlled, enabling the at least one beat frequency signal to avoid remaining in and shunting through cerebrospinal fluid proximate to the subject's spinal cord, thereby recruiting dorsal column fibers." Claim 15 has also been amended in a similar manner.

Support for the amendment can be found, for example, on page 2 lines 11-21, page 3 lines 15-23, and page 6, lines 15-20.

For example, on page 2, lines 11-21, Applicant described that SCS stimulates the dorsal column in a somewhat superficial manner where electrodes are attached to dura matter, and most of the current distribution remains in the cerebrospinal fluid (CSF) and does not project deeply into the dorsal column. In contrast, providing an interferential component to the electrode array of the SCS allows the crossing of the two signals wherein the resultant additive effect of the beat

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frequency produces deeper penetration of the signal and a higher resultant amplitude at the stimulation site because most of the beat frequency signal does not remain in or shunt through the CSF, for example. The interferential current would recruit larger numbers of dorsal column fibers and provide greater levels of pain relief and benefit to intractable pain patients.

On page 3, lines 15-23, for example, Applicant described that interferential current provides improved directional control, decreased accommodation/habituation and increased depth of penetration in comparison to other standard implantable stimulation systems and their accompanying surgical leads. The amplitudes of the outputs in the respective circuits may be modulated to increase the area of targeted stimulation. Interferential current allows improved directional control and depth of penetration in comparison to other stimulation techniques.

On page 6, lines 15-20, for example, Applicant described that the digital signal processor improves the accuracy and reliability of digital signals. The digital signal processor processes the multiple pulses from the signal generating source to approximate a sine-wave (pseudo-sine-wave or sine-wave-like). Thus, that type of current recruits larger numbers of dorsal column fibers and provides greater levels of pain relief.

III. Response to Rejection of Claims under 35 U.S.C. § 103

Claims 1-5, 7-8, 15-19 and 21-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Reiss in view of Holsheimer. Applicant asserts that the combination of references does not teach all aspects of the independent claims, and traverses the rejection by way of the Declaration under 37 CFR § 1.132 of William Carroll filed on March 10 2010.

As explained in the Declaration, a study was performed by the Neuronano Lund Research Center University in Sweden to determine stimulation effects created by an electrical stimulator that embodies the claimed invention. (*See* Exhibit B to the Declaration). The study compared

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stimulation effects created by the claimed invention to stimulation effects created by a conventional electrical stimulator, as described in the Holsheimer reference. The results of the study demonstrate that the activation thresholds in the dorsal column are significantly lower when using interferential current stimulation of the present invention than when using conventional stimulation as in Holsheimer. Furthermore, the same kind of results were obtained regardless of whether the conventional stimulation was performed in the parallel or crossed configuration. (*See*, e.g., Declaration, para. 19-20). More specifically, the activation thresholds were reduced by about 50% using interferential current stimulation of the present invention in either the parallel or crossed configuration. (*See*, e.g., Declaration, para. 19-20). Further, using conventional stimulation as in Holsheimer may spread stimulation through the cerebrospinal conductive fluid within the spinal cord causing chest and thoracic pain. (*See*, e.g., Exhibit A to the Declaration). In Holsheimer, most of the current distribution remains in the cerebrospinal fluid (CSF) and does not project deeply into the dorsal column to relieve pain, in contrast to the present invention. (Specification, p. 2).

The study also compared the stimulation effects created by the claimed invention to stimulation effects created by applying stimulation using conventional surface electrodes, as described in Reiss. (*See*, e.g., Declaration, para. 23-24). Electricity follows a path of least resistance, and applying stimulation on the surface of the skin using surface electrodes does not allow for effective stimulation through the vertebrae. *Id.* Accordingly, it would be impractical to attempt to achieve the stimulation effects seen in the results of the study in Exhibit A of the Declaration using surface stimulation as in Reiss because it would be highly likely that tissue damage and pain would be caused in the patient. *Id.*

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Using the interferential implantable electrode configuration of the present application enables for treatment of pain that cannot be effectively treated by either of the systems in Holsheimer or Reiss. Using the interferential implantable electrode configuration of the present application, interferential current recruits large numbers of dorsal column fibers and provides much greater levels of pain relief and benefit to intractable pain patients (Specification, p. 2), and enables "a majority of the at least one beat frequency signal [to be] directionally distributed and controlled, enabling the at least one beat frequency signal to avoid remaining in and shunting through cerebrospinal fluid proximate to the subject's spinal cord, thereby recruiting dorsal column fibers." (claim 1).

The different results achieved between the present application and either Holsheimer or Reiss are a dramatic improvement and are appropriately classified as a difference in kind, rather than one of degree so as to be evidence sufficient to rebut a *prima facie* case of obviousness. (MPEP § 716.02). Moreover, the results demonstrated by the study in Exhibit B to the Declaration are of a significant, practical advantage sufficient to rebut a *prima facie* case of obviousness. (MPEP § 716.02(a)(I)). Enabling for effective treatment of pain through stimulation of the dorsal column without the risks present in the systems in Holsheimer and Reiss (the risks in Reiss are so high as to prevent a practical application of Reiss for treatment) is significant for the population of patients with intractable pain.

IV. Response to Examiner's Comments

On page 4 of the Final Office Action mailed June 17, 2010, the Examiner stated that Applicant's Declaration argued facts not present in the claims, in that Reiss and Holsheimer would be impractical for treatment of pain through stimulation of the *Gracile nucleus and Pyramidal tract* in the dorsal column. The Examiner stated that the claims as written do not

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require the interferential stimulation to affect the Gracile nucleus or Pyramidal Tract. Applicant noted that the Declaration states in paragraph 10 that it is desired to provide deep stimulation through the dura mater of the spinal cord for activating the Gracile nucleus and Pyramid and other portions of the Dorsal Column using low levels of stimulation so as to avoid spreading of stimulation through the cerebrospinal fluid. The effect of activating the specific Gracile nucleus and Pyramid is used as an indicator that "deep stimulation" was achieved. Measuring and detecting stimulation of the Gracile nucleus and Pyramid is only one method of quantifying the results of the experiments.

In addition, as described in paragraph 15 of the Declaration, Adult rats were used in the experiments, and two pairs of stimulation electrodes were placed to a dura mater in an epidural space on the spinal cord in two configurations. The recording microelectrodes were inserted in the Gracile nucleus and the Pyramid in the brainstem of the rats, so as to measure a "depth" of stimulation of the spinal cord. By spinal cord stimulation, activating the pyramid tract fibers antidromically evoked volleys in the deep tracts that were recorded, thus giving information about depth of penetration of the stimulation. (*See*, Figure 1 of Exhibit B to the Declaration).

On page 5 of the Final Office Action mailed June 17, 2010, the Examiner acknowledged that Holsheimer fails to teach motivation that implantation of the electrode will decrease power consumption through minimizing activation needed to perform stimulation. The Examiner stated that this is considered to be factual. However, implanting electrodes as in Holsheimer may not guarantee a decrease in power consumption. Similarly, implanting Reiss' electrodes may not guarantee a decrease in power. In traditional SCS stimulation, only superficial stimulation of the dorsal column is achieved even when electrodes are attached to the dura matter in the

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epidural space. Most of the current distribution remains in the cerebrospinal fluid (CSF) (resulting in pain) and does not project deeply in to the dorsal column. (Specification, p. 2).

The Examiner further stated that a teaching-suggestion-motivation is not necessary to determine obviousness under *KSR*, and maintained that the combination of Reiss and Holsheimer would yield predictable results. However, again, the Examiner has provided no evidence that such results are "predictable" in view of traditional SCS stimulation techniques. In fact, using Holsheimer implantable electrodes in the Reiss system would not necessarily provide predictable results of effective treatment. The Declaration states in paragraphs 6-13 that in SCS, it is necessary to provide deep stimulation for effective pain relief, and that it is desired to provide deep stimulation through the dura mater of the spinal cord while also avoiding spreading of stimulation through the cerebrospinal fluid (which would cause pain). With SCS, if current is simply increased, the effect may be to spread stimulation through the cerebrospinal fluid, resulting in chest and thoracic pain. However, without a proper current level, deep penetration through the dura mater may not be achieved. The experiments described in the Declaration demonstrate that the present application enables one way to provide deep penetration through the dura mater without substantial spreading of the stimulation and resulting side effects. The Examiner has not provided factual evidence that combining the cited references would have the same alleged "predictable" result.

V. Conclusion

Applicant requests allowance of the claims at this time. Applicant requests that the Examiner call the undersigned at (312) 913-3331 with any questions or comments.

Respectfully submitted,

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